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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,459	05/31/2000	MERVYN JOSEPH FREDERICK	0/97322US	8345

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

15

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,459

Applicant(s)

FREDERICK ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1616

DETAILED ACTION

Receipt of Amendments and Remarks received July 30, 2003 is acknowledged. Claims 1-10 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is directed to “a method to avoid influence from a vaginal ring upon the environment...” which is vague and indefinite. It is unclear how a vaginal ring can affect the environment.

Claim 6 recites the term “PET” which is vague and indefinite. The examiner assumes the applicant is intending to claim “polyethylene terephthalate”. Therefore, the examiner suggests the following: polyethylene terephthalate (PET).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 4,692,143 to Gero in view of FR 2748994.

Gero teach a ready-to-use vaginal contraceptive contained in a porous polyurethane sponge. See abstract. The sponge is a generally open-celled polyurethane mass wherein a sting is looped diagonally thorough the sponge and tied taut in a loop for anchoring purposes. The loop forms a convenient means for withdrawing the sponge from the vaginal canal. See column 4, liens 1-14. The sealed foil packet comprises two opposing sheets or films heat or pressured sealed around the periphery to form an enclosure for the sponge and ensure sterility of the contents in the package. The sheets may comprise a foil-thermoplastic film laminate sealed together around the periphery. See column 4, lines 14-20. Note Gero's sponge contains a loop, which reads on applicant's ring.

Gero does not teach the use of a resealable package.

FR teaches a package for contraceptive wherein the packaging can be resealed with a flap on the pocket part f the package. The resealable package allows for convenient disposal of the used contraceptive. See abstract.

Art Unit: 1616

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Gero and FR and utilize a reclosable package. One would have been motivated to do so since FR teaches a reclosable package allows for convenient and hygienic disposal for contraceptive devices. Therefore, one would have been motivated to add the reclosable flap to Gero's package to provide for hygienic disposal of the contraceptive sponge.

Claims 1-4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 4,997,653 to Igarashi in view of JP 05-154170 in further view of FR 2748994.

Igarashi teaches intrauterine and vaginal preparations comprising a matrix base having a danazol effective in the shrinkage of endometriosis tissue and induction of pregnancy. See abstract. The intrauterine preparation is a vaginal ring. See example 4. Igarashi teaches the preparations must be sterile products on the basis of their usage and thus it is understood that the final product is packaged with heat-sealable aluminum packing materials. See column 4, lines 35-43.

Igarashi does not teach the specifics of the heat-sealable package. Further, Igarashi does not teach the use of a reclosable package.

JP teaches packaging material for contraceptives that prevents the influence of humidity on the material contained within. See abstract. The package comprises a primer layer (cellophane), aluminum foil (9 microns), a high-density polyethylene film (22 microns), and a sealant layer of ethylene-vinylacetate copolymer (32 microns). See Figure and abstract. The package is heat-sealed around the perimeter. See paragraph 0002.

Art Unit: 1616

FR teaches a package for contraceptive wherein the packaging can be resealed with a flap on the pocket part of the package. The resealable package allows for convenient disposal of the used contraceptive. See abstract.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Igarashi and JP and utilize JP's package material for Igarashi's vaginal ring. One would have been motivated to do so since JP teaches sterile packing for contraceptives that obviates the influence of humidity on the contents.

Further, it would have been obvious for one of ordinary skill in the art at the time the invention was made to look to the teachings of FR and utilize a reclosable package. One would have been motivated to do so since FR teaches a reclosable package allows for convenient and hygienic disposal for contraceptive devices. Therefore, one would have been motivated to add the reclosable flap to Igarashi and JP's package to provide for hygienic disposal of the contraceptive ring.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 4,997,653 to Igarashi in view of JP 7-223653.

Igarashi teaches intrauterine and vaginal preparations comprising a matrix base having a danazol effective in the shrinkage of endometriosis tissue and induction of pregnancy. See abstract. The intrauterine preparation is a vaginal ring. See example 4. Igarashi teaches the preparations must be sterile products on the basis of their usage and thus it is understood that the final product is packaged with heat-sealable aluminum packing materials. See column 4, lines 35-43.

Igarashi does not teach the specifics of the heat-sealable package.

Art Unit: 1616

JP teaches a laminated packaging bag comprising a seal that surrounds the bag and a sliding clasp fastener. The bag comprises laminated layers of paper/polyethylene/aluminum/polyethylene and cellophane(15-50 microns)/paper(50-100 microns/polyethylene (10-30 microns)/aluminum (7-10 microns)/polyethylene (20-50 microns). The packaging material is utilized for various products including, medical products and chemical material. See page 4 of translated document. The package provides air tightness and stability to the package contents. See page 5. Further, the package prevents the package from leaking. See page 6. On page 11, a polyester layer is taught.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Igarashi and JP and utilize JP's laminated bag for Igarashi's vaginal ring. One would have been motivated to do so since JP teaches a package that provides stability and air tightness for the contents contained within. Therefore, one would have been motivated to place Igarashi's ring in JP's bag since Igarashi's teaches the importance of a sterile package for the ring and JP's package provides such a package.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 4,997,653 to Igarashi in view of JP 7-223653 in further view of US patent 3,995,631 to Higuchi et al.

Igarashi teaches a vaginal ring contained in a sterile aluminum package. JP teaches a resealable package for medical products that comprises laminated layers of paper/polyethylene/aluminum/polyethylene and cellophane(15-50 microns)/paper(50-100 microns/polyethylene (10-30 microns)/aluminum (7-10 microns)/polyethylene (20-50 microns).

The references do not specify the use of polyethylene terephthalate.

Art Unit: 1616

Higuchi et al teach a device which may be a vaginal ring contained within flexible bag that is made of impervious material. See abstract and column 14, line 44. The bag may be made of material such as polyethylene or polyethylene terephthalate, etc. see column 8, lines 22-25.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Igarashi, JP, and Higuchi et al and substitute JP's polyethylene for instant polyethylene terephthalate. One would have been motivated to do so since Higuchi et al teach the functional equivalence of polyethylene or polyethylene terephthalate as impervious material to package products such as vaginal rings. Therefore, it is prima facie obvious to substitute one functional equivalent for another with the expectation of success.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

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